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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,391	11/12/2003	Gerald B. Pier	B0801.70256US01	8225

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,391	PIER ET AL.	
	Examiner	Art Unit	
	CHRISTIAN L. FRONDA	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,34,40,42,49,53,63,69-71,73,84,90,107,116 and 134-140* is/are pending in the application.

4a) Of the above claim(s) *1,10,34,42,49,53,73,84,90,107 and 116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63,69-71 and 134-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 02/14/2008 has been entered.

2. Claims 1, 10, 34, 40, 42, 49, 53, 63, 69-71, 73, 84, 90, 107, 116, 134-140 are pending in the application. Claims 1, 10, 34, 42, 49, 53, 73, 84, 90, 107 and 116 have been previously withdrawn from consideration as drawn to a non-election invention.

Upon further consideration claims 134, 135, and 139 will be rejoined with claims of elected Group VII. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 63, 69-71, and 134-140 are under consideration in this Office Action. The previous rejections and grounds of rejection have been withdrawn. New rejections and new grounds of rejection are presented in the instant Office Action.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 63, 69-71, and 134-140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 63 and 71 are vague and indefinite for reciting the phrase "*ica* nucleic acid comprising nucleotides 2330-5745 of SEQ ID NO: 3 (GenBank Accession No. AF086783)". The metes and bounds are uncertain since it is not clear if the claim is limited to 2330-5745 of SEQ ID NO: 3 or GenBank Accession No. AF086783. Since GenBank Accession records are known to be revised, it is unclear as to what specific nucleotide sequence is being claimed. Furthermore, it is not clear if SEQ ID NO: 2 or any other nucleic acid that hybridizes to SEQ ID NO: 2 under the recited conditions is being claimed because the claim recites the phrase "spans nucleotides 23 and 29 of SEQ ID NO: 2, has an addition, deletion or substitution of at least two nucleotides in a region between and including nucleotides 24 and 28 of SEQ ID NO: 2". Since the specific nucleic acid that hybridizes to SEQ ID NO: 2 is not disclosed, it is unclear as what nucleotide positions are being referred to. Dependent claims 69-70, 134- 140 are also rejected because they do not correct the defect.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 63, 69-71, and 134-140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are directed toward the USPTO Written Description Training Materials made available to the public on 04/11/2008 for information regarding examination of patent claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph.

According to MPEP 2163, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v.Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed.Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Claims 63 is a genus claims encompassing a genus of nucleic acid molecules which hybridizes under stringent conditions at 65°C in hybridization buffer, washing at room temperature with 0.15M sodium chloride, 0.015M sodium citrate, pH 7 (SSC) and at 68°C with 0.1-0.5 x SSC, 0.1 sodium dodecyl sulphate to a nucleic acid molecule having a sequence of SEQ ID NO:2, spans nucleotides 23 and 29 of SEQ ID NO: 2, has an addition, deletion or substitution of at least two nucleotides in a region between and including nucleotides 24 and 28 of SEQ ID NO:2, and enhances production of poly-N-acetyl glucosamine when operably linked to an *ica* nucleic acid comprising nucleotides 2330-5745 of SEQ ID NO: 3, or a complement thereof.

Claim 73 is a genus claim encompassing a genus of nucleic acid molecules which are fragments of SEQ ID NO: 1 or complements, wherein the fragments spans nucleotides 23 and 24 of SEQ ID NO: 1 and enhances production of poly-N-acetyl glucosamine when operably linked to an *ica* nucleic acid comprising nucleotides 2330-5745 of SEQ ID NO: 3.

The scope of each genus includes many nucleic acid molecules with widely differing nucleotide sequences and structures, where the genus is highly variable because a significant number of structural and biological differences between genus members exists, and each genus includes partial structures of SEQ ID NO: 2 and SEQ ID NO: 1, respectively.

While the specification discloses an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 2 and an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1, the specification, however, does not describe and define any structural features, nucleotide sequences, and/or biological functions that are commonly possessed by members of each genus. There is no art-recognized correlation between any structure of each claimed genus of nucleic acid molecules and their biological function such as enhancing production of poly-N-acetyl glucosamine. Those of ordinary skill in the art would not be able to

identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 2 under the recited conditions would also result in enhancement of poly-N-acetyl glucosamine production. Similarly, those of ordinary skill in the art would not be able to identify without further testing which of those fragments of SEQ ID NO: 1 would also result in enhancement of poly-N-acetyl glucosamine production

MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose additional nucleic acid molecules as encompassed by the claims. As such the disclosure of the above mentioned isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 2 and isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1 is insufficient to be representative of the attributes and features common to all the members of each claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class, where the specification provided only the bovine sequence.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the each claimed genus of nucleic acid molecules. Dependent claims 69, 70, and 134-140 are also rejected because they do not correct the defect of claim 63 or claim 71.

8. Claims 63, 69-71, and 134-140 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising SEQ ID

NO: 2 or a full complement thereof, and an isolated nucleic acid molecule comprising SEQ ID NO: 1 or a full complement thereof; **does not** reasonably provide enablement for any nucleic acid molecule or any complement thereof as recited in claim 63, and any nucleic acid molecule or any complement thereof as recited in claim 71. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claim 63 encompass any nucleic acid molecule which hybridizes under stringent conditions at 65°C in hybridization buffer, washing at room temperature with 0.15M sodium chloride, 0.015M sodium citrate, pH 7 (SSC) and at 68°C with 0.1-0.5 x SSC, 0.1 sodium dodecyl sulphate to a nucleic acid molecule having a sequence of SEQ ID NO:2, spans nucleotides 23 and 29 of SEQ ID NO: 2, has an addition, deletion or substitution of at least two nucleotides in a region between and including nucleotides 24 and 28 of SEQ ID NO:2, and enhances production of poly-N-acetyl glucosamine when operably linked

to an *ica* nucleic acid comprising nucleotides 2330-5745 of SEQ ID NO: 3, or any complement thereof.

The nature and breadth of the claim 63 encompass any nucleic acid molecule which are fragments of SEQ ID NO: 1 or complements, wherein the fragments spans nucleotides 23 and 24 of SEQ ID NO: 1 and enhances production of poly-N-acetyl glucosamine when operably linked to an *ica* nucleic acid comprising nucleotides 2330-5745 of SEQ ID NO: 3.

The specification discloses an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 2 and an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1. However, the specification does not provide guidance, prediction, and working examples showing a correlation between any structure, nucleotide composition, and nucleotide sequence of the nucleic acid molecules as claimed and its biological function such as enhancing production of poly-N-acetyl glucosamine. There is no art-recognized correlation between any structure, nucleotide composition, and nucleotide sequence of the nucleic acid molecules as claimed and its biological function of enhancing production of poly-N-acetyl glucosamine. Furthermore, the recitation of the phrase "a complement" (see claim 63) or "complements" (see claim 71) encompasses fragments, including dinucleotide fragments for which the specification provides no guidance, prediction, and working examples for using such dinucleotide fragments.

Thus, one must perform an enormous amount of trial and error experimentation to search and screen for the claimed nucleic acids from any biological source or chemically synthesize the nucleic acids and determine if they can be used to enhance production of poly-N-acetyl glucosamine. General teaching regarding screening and searching for the claimed invention using the aggregation assays stated in the specification is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use to make and use the entire scope of the claimed invention recited in claims 63, 69-71, and 134-140.

Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970). Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Patent Examiner
Art Unit 1652